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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/502,293	04/08/2005	Ian David Worthington	Q82451	9187
23373	7590	10/03/2005	EXAMINER	
SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037			PATEL, MITAL B	
			ART UNIT	PAPER NUMBER
			3743	

DATE MAILED: 10/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/502,293

Applicant(s)

WORTHINGTON, IAN DAVID

Examiner

Mital B. Patel

Art Unit

3743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration:
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 12 is/are rejected.
- 7) ☒ Claim(s) 8-11 and 13-17 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 July 2004 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 7/22/04.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Specification***

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

#### **Arrangement of the Specification**

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT
- (e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC (See 37 CFR 1.52(e)(5) and MPEP 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text are permitted to be submitted on compact discs.) or REFERENCE TO A "MICROFICHE APPENDIX" (See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.)
- (f) BACKGROUND OF THE INVENTION.
  - (1) Field of the Invention.
  - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (g) BRIEF SUMMARY OF THE INVENTION.
- (h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (i) DETAILED DESCRIPTION OF THE INVENTION.
- (j) CLAIM OR CLAIMS (commencing on a separate sheet).
- (k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-7 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Lieberman (US 4,627,433).

3. **As to claim 1**, Lieberman teaches a tracheostoma valve including a valve housing (**See Figs. 11,12**) defining a valve cavity and having at least one rearward and at least one forward aperture such as to define an air flow passage through the said valve cavity between the rearward and forward apertures; and further comprising within the valve cavity a valve member **112** deployable from a first collapsed configuration under vegetative breathing pressure wherein the said air flow passage is open to a second expanded configuration under speech pressure whereat the valve member acts to restrict flow through said air flow passage, wherein the valve member comprises a rear portion fixedly mounted to an inner surface of the valve housing rearward of the forward aperture so as to surroundingly and sealingly engage over the rearward aperture, a forward portion, and a collapsibly expandable sleeve portion **181** provided therebetween to surroundingly define a part of the air flow passage, such that the forward portion is deployable from a position in the unexpanded configuration whereat the air flow passage is open to a position in the expanded configuration whereat the forward portion acts to restrict air flow through the air flow passage (**See Col. 7-8**).

4. **As to claim 2**, Lieberman teaches a tracheostoma valve wherein the sleeve portion is structured to facilitate expansion of the valve member in use (**See Col. 7-8**).
5. **As to claim 3**, Lieberman teaches a tracheostoma valve wherein the sleeve portion has a concertina structure **183**.
6. **As to claim 4**, Lieberman teaches a tracheostoma valve wherein the sleeve portion is resiliently biased to the unexpanded configuration (**See Col. 7-8**).
7. **As to claim 5**, Lieberman teaches a tracheostoma valve wherein the sleeve portion is fabricated from flexible material and biased to the unexpanded configuration by provision of separate biasing means **182**.
8. **As to claim 6**, Lieberman teaches a tracheostoma valve wherein the sleeve is fabricated from inherently resiliently expandable material, such as elastomeric material, and is so configured that the inherent resilience biases the valve member the unexpanded configuration (**See Col. 7-8**).
9. **As to claim 7**, Lieberman teaches a tracheostoma valve wherein the forward portion incorporates a valve aperture and a valve seating surface is provided within the valve cavity on an inner surface of the valve housing such that when the valve member is in the expanded configuration the forward portion of the valve member seats against the valve seating surface in sealing manner to effect closure of the valve aperture therein and hence generally occlude the air flow passage (**See Figs. 11,12**).
10. **As to claim 12**, Lieberman teaches a tracheostoma valve wherein the valve housing is provided with an integral rearwardly extending cannular portion adapted to be retained within the stoma of a tracheotomy patient to provide a breathing passage in

Art Unit: 3743

use from the trachea of the patient to the valve, or a rear face of the housing is adapted for releasable engagement with a forward surface of a cannular device already so adapted for provision within the stoma of a patient (**See Col. 7-8**).

***Allowable Subject Matter***

11. Claims 8-11, 13-17 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Conclusion***

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 6921417, US 6193751, US 5727594, US 4809693, US 4582058, US 4040428.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mital B. Patel whose telephone number is 571-272-4802. The examiner can normally be reached on Monday-Friday (11:00-7:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on 571-272-4791. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3743

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Mital B. Patel  
Primary Examiner  
Art Unit 3743